# 114.3 CMR 31.00: PRESCRIBED DRUGS

Section



## 31.01: General Provisions

(1) Scope, Purpose and Effective Date. 114.3 CMR 31.00 shall govern the determination of rates to be used by all governmental units for prescribed drugs dispensed to publicly-aided patients by eligible pharmacy providers. The rates set forth 114.3 CMR 31.04 shall be effective as of February 1, 2005. The payment rates set forth in 114.3 CMR 31.00 also apply to individuals covered by M.G.L. c. 152 (the Worker's Compensation Act) as set forth in 114.3 CMR 40.02(4)(a)1.

(2) Coverage. 114.3 CMR 31.00 and the rates of payment contained herein shall apply to prescribed drugs dispensed by eligible pharmacy providers to publicly-aided patients. The rates of payment under 114.3 CMR 31.00 are full compensation for professional services rendered, as well as for any related administrative or supervisory duties.

(3) Authority. 114.3 CMR 31.00 is adopted pursuant to M.G.L. c. 118G.

## 31.02: General Definitions

Actual Acquisition Cost (AAC). The amount a pharmacy pays for a drug, net of discounts, rebates, charge backs, and other adjustments to the price of the drug.

Actual Package Size. The package size of any drug for which a most frequently purchased package size has not been determined by the Division shall be the actual package size as indicated by the National Drug Code (NDC) listed on the container from which the pharmacist dispenses the drug.

Compounded Drug. Any drug, excluding cough preparations, in which two or more ingredients are extemporaneously mixed by a registered pharmacist.

Dispensing Fee. The fee paid, over and above the ingredient cost of the drug, to eligible pharmacy providers by governmental units and purchasers under the Worker's Compensation Act for dispensing prescribed drugs to publicly-aided individuals and/or industrial accident patients.

Drug. A substance containing one or more active ingredients in a specified dosage form and strength and authorized by the purchasing governmental unit or purchaser under M.G.L. c. 152. Each dosage form and strength is a separate drug.

Eligible Pharmacy Provider. Eligible Pharmacy Providers are defined as: (1) pharmacies, as defined in 114.3 CMR 31.02; (2) clinic pharmacies licensed by the Department of Public Health in accordance with the provisions of M.G.L. c. 111 and which also meet the current conditions of participation of the purchasing governmental unit or purchaser under M.G.L. c. 152; and (3) 340B Covered Entities.

Estimated Acquisition Cost (EAC). An estimate of the price generally and currently paid by non-340B covered entity eligible pharmacy providers for the most frequently purchased package size of a drug. The EAC shall be the drug wholesaler's acquisition cost (WAC) plus 5 percent.

Federal Upper Limit. The Federal Upper Limit as established by the Centers for Medicare and Medicaid Services (CMS) in 42 CFR 447.332.

Fiscal Year. The annual accounting period adopted by an eligible pharmacy provider.

Governmental Unit. The Commonwealth, any department, agency, board or commission of the Commonwealth, and any political subdivision of the Commonwealth.

Health Insurer. A private or public entity, including Medicare, that has a health plan or policy under which it pays for medical services provided to a member. An endorsed discount card issued in accordance with Section 1860D-31(a) of the Social Security Act is not considered a health insurance plan or policy.

Legend Drug. Any drug for which a prescription is required by applicable federal and/or state laws or regulations.

Massachusetts Upper Limit. For multiple source drugs, an amount equal to one hundred thirty percent of the price of the least costly therapeutic equivalent as listed in any United States published or other United States public source for the most frequently purchased package size. The Massachusetts Upper Limit is also known as the Maximum Allowable Cost (MAC).

Most Frequently Purchased Package Size. The package size of a drug most frequently purchased by eligible pharmacy providers based

on utilization data compiled by MassHealth. Thus, that NDC number which is most often paid by the MassHealth, and verified by audit, if necessary, will be considered the most frequently purchased package size.

Multiple Source Drug. A drug marketed or sold by two or more manufacturers or labelers or a drug marketed or sold by the same manufacturer or labeler under two or more different names.

National Drug Code (NDC) Number. A unique number issued by the United States Food and Drug Administration to identify drug products. The NDC number has three components: the first component identifies the drug manufacturer ("Labeler No."); the second component identifies the product ("Product No."); and the third component identifies the package size ("Pkg.").

Non-Legend Drug. Any drug for which no prescription is required by federal or state law.

Pharmacy. Any pharmacy registered by the Board of Registration in Pharmacy in accordance with the provisions of M.G.L. c. 112.

Provider. Anyone who furnishes services or supplies to publicly-aided and/or industrial accident patients for which he is entitled to reimbursement from a purchasing governmental unit or a purchaser under M.G.L. c. 152.

Publicly Aided Individual. A person for whose medical or other services a governmental unit is in whole or in part liable under a statutory public program.

Required Filing Date. The day by which all required reports must be submitted to the Division.

Required Reports. Any Division reports requesting data and information, including the Division of Health Care Finance and Policy's Massachusetts Pharmacy Costs report.

Single Source Drug. A drug marketed or sold by only one manufacturer or labeler under one proprietary name.

Unit-Dose Packaging. An individual drug product container usually consisting of foil, molded plastic, or laminate with indentations for a single solid oral dosage form, with any accompanying materials or components, including labeling. Each individual container fully identifies the drug and protects the integrity of the dosage. For purposes of 114.3 CMR 31.00, an assemblage of multiple, unlabeled single doses (traditional "bingo cards" or "bubble packs") is not unit-dose packaging.

Unit Dose-Return Fee. The fee paid to eligible pharmacy providers, by governmental units only, for accepting returned drugs in unit-

dose packaging, as defined in 114.3 CMR 31.02, and in accordance with 130 CMR 406.446.

Usual and Customary Charge. The lowest price that a pharmacy charged or accepted from any health insurer or pharmacy benefit manager for the same quantity of a drug dispensed to a Massachusetts resident on the same date of service. When an insurer and the provider have a contract that specifies that the insurer will pay an average or similarly computed fixed amount for multiple categories of drugs with different acquisition costs, the fixed amount will not be the provider's usual and customary charge. Drugs will be identified by NDC number.

340B Covered Entities. Facilities and programs eligible to purchase discounted drugs through a program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992.

340B Drug Pricing Program. A program established by Section 340B of Public Health Law 102-585, the Veterans Health Act of 1992, permitting certain grantees of federal agencies access to reduced cost drugs for their patients.

31.03: Filing and Reporting Requirements

(1) Required Reports and Records. Each eligible provider shall:
(a) file such data and information as the Division shall reasonably require.
(b) certify the accuracy and truthfulness of all data, information, reports, books, and records submitted to the Division.
(c) make available to the Division all reports, books, and records relating to its operation for audit.
(d) 340B Covered Entities must file, on a quarterly basis, additional data as described in the Division's 340B-1 Report.

(2) Filing Dates.
(a) All required reports and records shall be filed by eligible pharmacy providers with the Division within the time period specified by the Division in its request.
(b) The Division may, for cause, extend the filing date for submission of required reports and records.

(3) Penalties for Eligible Pharmacy Providers. The Division may reduce the dispensing fee and/or take other action against pharmacies pursuant to its delegated powers under M.G.L. c. 118G for failure to comply with 114.3 CMR 31.03(1) and (2).

31.04: Pharmacy Payment for Legend Drugs

(1) Pharmacy Payment for Multiple Source Drugs. Payment to pharmacy providers for such drugs dispensed shall not exceed the lowest of:

(a) The federal upper limit of the drug, if any, plus the appropriate dispensing fee as listed in 114.3 CMR 31.06; or

(b) The Massachusetts upper limit of the drug, if any, plus the appropriate dispensing fee as listed in 114.3 CMR 31.06; or

(c) The estimated acquisition cost of the drug, plus the appropriate dispensing fee as listed in 114.3 CMR 31.06; or

(d) The usual and customary charge.

(2) Pharmacy Payment for All Other Drugs. These include single source drugs and brand name drugs which have been certified as medically necessary (i.e., for which the prescriber has designated "no substitution" and "brand name medically necessary" on the prescription form). Payment to eligible pharmacy providers for such drugs dispensed to publicly-aided patients shall not exceed the lower of:

(a) The estimated acquisition cost of the drug plus the appropriate dispensing fee as listed in 114.3 CMR 31.06; or

(b) The usual and customary charge.

(3) Rate Limitation. The rates determined under 114.3 CMR 31.04 shall not, in the aggregate, exceed the upper limits established pursuant to 42 CFR 447.331.

31.05: Pharmacy Payment for Non-Legend Drugs

Pharmacy Payment for Non-Legend Drugs. Payment to eligible pharmacy providers for a non-legend drug dispensed to a publicly-aided patient or an industrial accident patient shall not exceed the lowest of:

(1) The Massachusetts Upper Limit of the drug plus the appropriate dispensing fee as listed in 114.3 CMR 31.06; or

(2) the estimated acquisition cost of the drug plus the appropriate dispensing fee as listed in 114.3 CMR 31.06; or

(3) the usual and customary charge.

31.06: Pharmacy Dispensing Fees

(1) Prescribed Drugs. The dispensing fee paid to eligible pharmacy providers for dispensing prescribed drugs to publicly-aided and/or industrial accident patients shall be $3.00 per prescription.

(2) Compounded Drugs. The dispensing fee paid to eligible pharmacy providers for dispensing prescribed compounded drugs to publicly-aided and/or industrial accident patients shall be the dispensing fee set forth in 114.3 CMR 31.06(1) plus:

(a) An additional $1.00 for:
1. compounding ointments or solutions; or
2. preparing solutions (excluding cough preparations) which involve the weighing of ingredients; or

(b) An additional $2.00 for:
1. compounding suppositories; or
2. compounding capsules, tablets, triturates or powders.

31.07: Payment for 340B Covered Entities for Legend and Non-Legend Drugs

340B Covered Entities will be paid their actual acquisition cost of the drug plus a $10.00 dispensing fee for drugs obtained through the 340B Drug-Pricing Program.

31.08: Unit-Dose-Return Fee.

The fee paid to eligible pharmacy providers that dispense drugs in nursing facilities for accepting returned drugs in unit-dose packaging, in accordance with 130 CMR 406.446, shall be $5.00 per unit-dose package.

31.09: Payment for Drugs Dispensed as part of an Innovative Program System for Publicly-Aided Patients

Government units may apply to the Division for approval of written contractual agreements containing programmatical and reimbursement provisions entered into with eligible pharmacy providers for drugs dispensed to publicly-aided patients. Approval of the contractual agreement by the Division shall constitute approval of the rates of payment set forth in the reimbursement provisions of the contract.

31.10: Severability of the Provisions of 114.3 CMR 31.00

The provisions of 114.3 CMR 31.00 are severable, and if any provision of 114.3 CMR 31.00 or application of such provisions to any eligible pharmacy provider or any circumstances shall be held to be invalid or unconstitutional, such invalidity shall not be construed to affect the validity or constitutionality of any remaining provisions of 114.3 CMR 31.00 or application of such provisions to any eligible pharmacy providers or circumstances other than those held invalid.

REGULATORY AUTHORITY

114.3 CMR 31.00: M.G.L. c. 118G.